



## Columbia University Laser Vision Center

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### Why Choose Columbia?

The Columbia University Laser Vision Center is part of the Department of Ophthalmology at the world-renowned Edward S. Harkness Eye Institute. We are part of a tradition of excellence in both clinical medicine and research dating back to the founding of the Institute in 1932. Our physicians pioneered the development of lasers for vision correction, having pioneered the use of excimer lasers for corneal refractive surgery. Today, Columbia continues to be recognized for its excellence in laser vision surgery and research.

Columbia University's Laser Vision Center offers a full spectrum of vision correction options from LASIK to PRK. Our board certified ophthalmologists are some of the top eye surgeons in the field. During your initial screening evaluation, our physician not only determines if you are a candidate for vision corrective surgery, but also provides a comprehensive eye examination to screen for any other conditions that may affect the outcome of the procedure, as well as the overall health of your eyes and vision.

### What to Expect Before the Procedure?

**Initial Screening Visit** – this is a free consultation provided by a certified ophthalmic support staff to determine the initial refractive state of the eye. **For contact lenses users, please remove soft contact lenses for at least 1 week prior to your evaluation and hard contact lenses for 2 weeks prior to your evaluation.**

**Laser Vision Correction Dilated Examination** – This examination is to determine your candidacy for refractive surgery. There is a \$250, non-refundable fee for this examination that is not covered by insurance. This evaluation constitutes a well care ophthalmologic examination. It includes, but is not limited to, the diagnostic imaging, refraction, and dilation of the eye. This exam is provided by certified ophthalmic support staff and by a board-certified ophthalmologist. Based on your examination, your physician will the different type of surgical options for you and set a procedure date.

**To schedule an appointment, please call (212) 342-3746.**

## Laser Vision Correction Surgery Waiver Form

(Please bring this form to your initial screening visit)

### Laser Vision Correction Screening\*

This is a free consultation provided by certified ophthalmic support staff to determine the initial refractive state of the eye. This exam in no way replaces a complete ophthalmic evaluation performed by an ophthalmologist and is not intended to diagnose or treat any other condition of the eye.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**\* Please remember to keep your contact lenses off for at least one (1) week prior to your screening visit.**

### Laser Vision Correction Dilated Examination

This examination is to determine your candidacy for refractive surgery. There is a \$250, non-refundable fee for this examination that is not covered by insurance. This evaluation constitutes a well care ophthalmologic examination. It includes, but is not limited to, the diagnostic imaging, refraction, and dilation of the eye. This exam is provided by certified ophthalmic support staff and by a board-certified ophthalmologist.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Vision Correction Surgery Pre- and Post-Operative Instructions

### **Before Your Surgery**

On the day of surgery, please remember the following:

1. Do not wear **any** make-up. Do not wear any mascara or eyeliner one (1) day prior to your surgery.
2. Do not wear **any** perfume or cologne, including any fragrant body lotion or cream.
3. Do not wear any contact lenses for at least *1 week* prior to your surgery for *regular soft lenses*, and *2 weeks* prior to your surgery for *toric and hard lenses*.
4. Arrive 15-20 minutes prior to your procedure time.
5. Read, sign and date your consent forms.
6. Arrange for transportation or for someone to drive you home after surgery.
7. Fill any needed prescriptions.

### **After Your Surgery**

1. It is recommended that you keep your eyes closed for 5-6 hours following the procedure. No television, reading, or computer use on the day of surgery.
2. Rest and use your drops during the first 24 hours after surgery, but do not interrupt sleep to take drops.
3. Do not drive for at least 12 hours after surgery.
4. Use clear protective shield(s) while sleeping.
5. Do not wear eye make-up for at least one week after surgery.
6. When you shower, please keep your eyes closed and away from tap water, soap and shampoo. Alternatively, you can wear protective shields.
7. Do not participate in contact/impact sports for 2-4 weeks. Golf and mild aerobic exercise is usually fine within a few days, or at your physician's discretion.
8. Protective eyewear must be worn when participating in any sporting activity.
9. No swimming, hot tub, sauna or steam bath for 4 weeks after surgery.
10. No yard, garden, or wood work for 1 week after surgery.
11. When leaving after your surgery, avoid sitting in the front of the car that is equipped with airbags.
12. When you are outside, please wear protective sunglasses as you will be sensitive to light.

# **Facts You Need to Know About Laser Assisted In Situ Keratomileusis (LASIK) and Photorefractive Keratectomy (PRK) Surgery**

## **Patient Information Booklet**

### **LASIK:**

**Nearsighted Patients (0 to -14.0 diopters) with or without  
-0.5 to -5.0 Diopters of Astigmatism**

**Farsighted Patients (+0.5 to +5.0 diopters) with  
up to +3.0 Diopters of Refractive Astigmatism**

**Mixed Astigmatism Patients ( $\leq$  6.0 diopters of astigmatism)**

### **PRK:**

**Nearsighted Patients (-1.0 to -12.0 diopters) or  
Nearsighted Patients (0 to -12.0 diopters) with  
up to -4.0 Diopters of Astigmatism**

**Farsighted Patients (+1.0 to +6.0 diopters) with  
no more than 1.0 Diopter of Refractive Astigmatism**

**Farsighted Patients (+0.5 to +5.0 diopters) with  
+0.5 to +4.0 Diopters of Refractive Astigmatism**

**Please read this entire booklet. Discuss its contents with  
your doctor so that all your questions are answered to  
your satisfaction. Ask any questions you may have  
before you agree to the surgery.**

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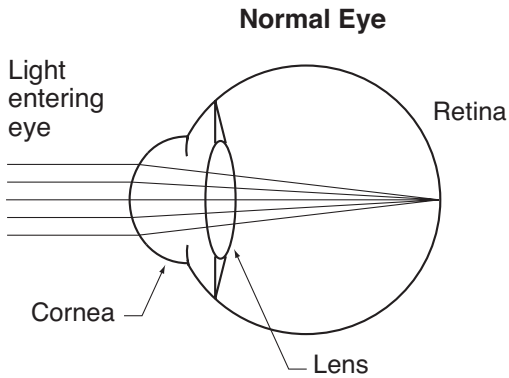
## **Introduction**

The information in this booklet is provided to help you decide whether to have Photorefractive Keratectomy (PRK) or Laser Assisted In Situ Keratomileusis (LASIK) laser surgery. LASIK and PRK may be used to correct or partly correct nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. Some other ways to correct these conditions are by wearing glasses or contact lenses, or by undergoing other kinds of refractive surgery such as radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK (also called laser refractive surgery or laser vision correction) are completely different from RK and ALK.

Your doctor may recommend laser vision correction (PRK or LASIK) for both eyes. However, sometimes it is better to have laser vision correction done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Please read this booklet completely. Discuss any questions with your doctor before you decide if laser vision correction is right for you. Only an eye care professional trained in laser vision correction can determine whether you are a suitable candidate. Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.

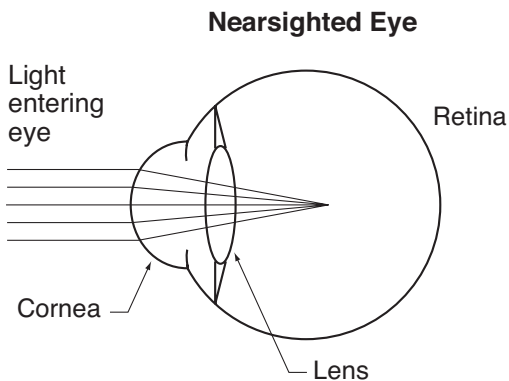
## How the Eye Functions



The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of

the eye's focusing power, and the lens inside the eye provides the other third.

## Nearsightedness



Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred. This condition is called nearsightedness, or myopia. Myopia usually starts in childhood and gets progressively worse through adolescence. It usually stops changing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

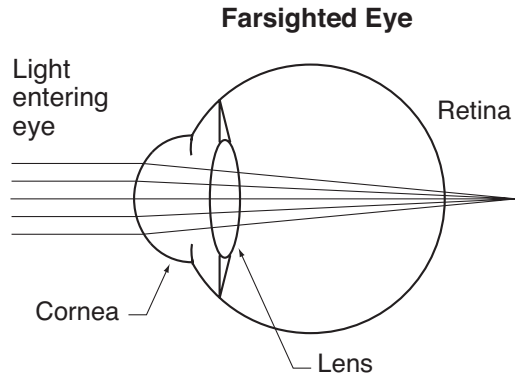
progressively worse through adolescence. It usually stops changing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

Nearsightedness can be corrected by any method that reduces the total refractive power of the eye. Eyeglasses and contact lenses do this by putting in front of the eye “negative” lenses that are thicker at the edge than in the center. PRK and LASIK treatments correct nearsightedness by flattening the central part of the cornea to reduce the total refractive power of the eye.

## Farsightedness

In farsightedness the image focuses beyond the retina. In our youth, the natural accommodating (focusing) power of the eyes often compensates for farsightedness. But as we age, our eyes become less able to accommodate. For this reason, farsightedness

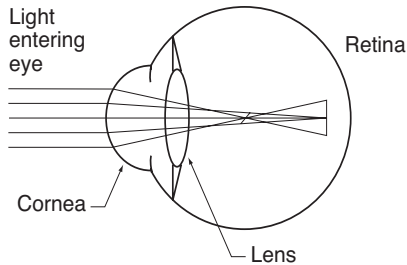
most commonly becomes a problem later in life. Many farsighted eyes do not need correction until the individuals reach their forties or fifties. Farsightedness can be corrected by any method that increases the total refractive power of the eye. Eyeglasses and contact lenses do this by putting in front of the eye “positive” lenses that are thicker in the center than at the edge. PRK and LASIK treatments correct it by making the central part of the cornea more steeply curved.



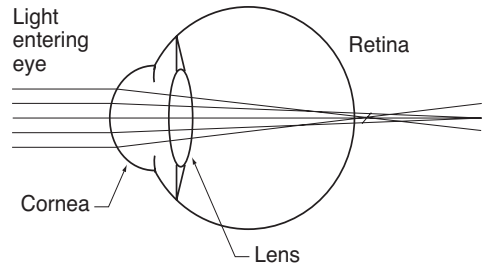
## Astigmatism

Astigmatism corrections bring all rays of light from different focal points to one focal point. Astigmatism may be all myopic (nearsighted), hyperopic (farsighted), or a combination of both (mixed). PRK and LASIK treatments correct astigmatism by altering the central cornea by different amounts at different radial orientations to correct for the uneven focus of light rays.

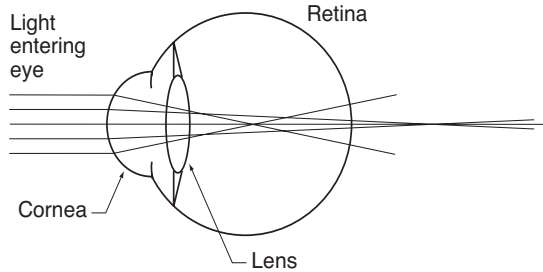
**Nearsighted and Astigmatic Eye**



**Farsighted and Astigmatic Eye**



**Mixed Astigmatic Eye**

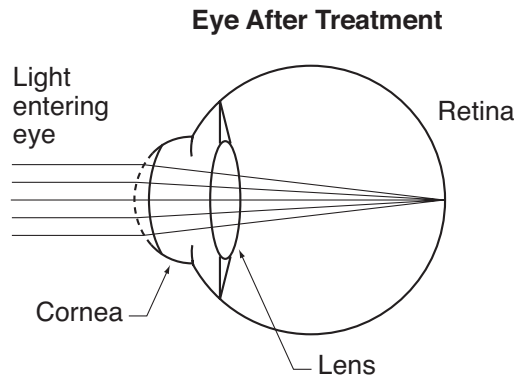


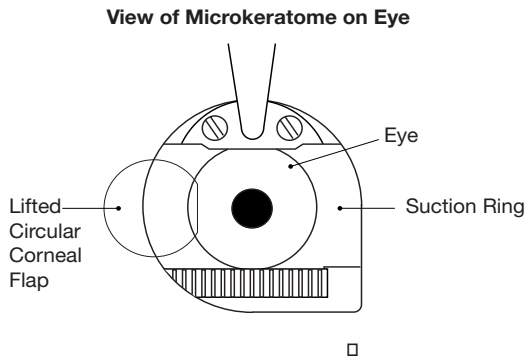
## What are PRK and LASIK?

PRK is laser surgery to correct refractive errors including nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. To correct nearsightedness, the excimer laser beam is applied to flatten the front of the cornea by removing small amounts of tissue from the front of the cornea.

To correct farsightedness, the excimer laser beam is applied to steepen the front of the cornea by removing small amounts of tissue from a ring-shaped area around the center of the cornea. To correct astigmatism, the excimer laser beam removes small amounts of tissue from the corneal surface that correspond to the cornea's astigmatic shape.

An excimer laser produces a powerfully focused beam of ultraviolet light. The laser is controlled by the surgeon. It produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) undisturbed. PRK and LASIK differ from RK. RK uses a knife to make deep cuts around the center of the cornea.





LASIK is similar to PRK, but does not treat the front surface of the cornea. The doctor uses an instrument called a *microkeratome* to create a circular flap of corneal tissue. The flap is then lifted from the outer portion of the cornea while the surgeon uses the excimer laser to remove

small amounts of underlying tissue from the exposed cornea. The corneal flap is then manually repositioned.

## Benefits

LASIK and PRK surgery may reduce overall myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (myopic, hyperopic, and mixed) in the power ranges and indications as listed on the cover of this booklet. These treatments help to reduce or eliminate dependency upon contact lenses or glasses.

## Risks

As with any surgical procedure there are risks associated with laser vision correction. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional laser refractive surgery in the same eye.

### IMPORTANT:

**You may need reading glasses after laser surgery even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.**

## The First Week Following Surgery

- Moderate pain and discomfort may last for up to 4 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.

## The First Two To Six Months Following Surgery

- Your intraocular pressure may increase due to use of anti-inflammatory medications. This is usually resolved by drug therapy or by stopping the anti-inflammatory medication.
- Your cornea may become hazy or cloudy enough to affect your vision. This haze typically disappears over time, but some patients may continue to experience some level of haze.

## One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail later in this booklet (see the section titled Long-Term Post-Treatment Safety Problems).

## Contraindications

You should **NOT** have laser refractive surgery if:

- You have collagen vascular, autoimmune, or immunodeficiency diseases (for example, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease).
- You are taking one or both of the following medications:
  - Accutane\* (isotretinoin).
  - Cordarone† (amiodarone hydrochloride).

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\* *Accutane is a registered trademark of Hoffman-La Roche Inc.*

† *Cordarone is a registered trademark of Sanofi.*



## Warnings

Your treatment result might not be as good with higher corrections of refractive error.

Discuss with your doctor if:

- Your nearsightedness, astigmatism, or farsightedness is changing.
- You are diabetic or have severe allergies.
- You have a history of *Herpes simplex* or *Herpes zoster* of the eye.

## Precautions

The PRK clinical trials included only 21 out of 200 eyes with nearsightedness between -10 and -12 diopters and 13 out of 275 eyes with farsightedness between +4 and +6 diopters. These populations were not sufficient to determine the level of effectiveness and complication rates for patients with severe nearsightedness or severe farsightedness.

If you have more than +4.0 D of farsightedness with or without astigmatism, a portion of your farsightedness may return. For patients with farsightedness with astigmatism, there is a 36% chance of demonstrating some residual (1 diopter or more) farsightedness at 1 year after surgery.

LASIK treatment for astigmatism at or below + 1.0 diopter may not be effective in some patients. The treatment can cause large changes in the direction of astigmatism without reducing the amount. This type of result may cause visual distortions that are more disturbing than the original astigmatism.

LASIK treatment for mixed astigmatism may leave you farsighted in addition to reducing your astigmatism. Patients in mixed astigmatism clinical trials were on average 0.3 diopter farsighted, with more farsightedness occurring in patients who were also farsighted before treatment.

The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined. Following laser refractive surgery, you may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. If you are under age 30 or have a large pupil size and have laser refractive surgery for treatment of astigmatism, you are more likely to experience problems with your vision under poor lighting conditions.

The safety and effectiveness of the VISX STAR™ Excimer Laser Systems have **NOT** been established:

- In eyes with corneal disease or abnormality (for example, scar, infection, etc.).
- In eyes with previous surgery or injury to the center of the cornea where the surgery will be performed.
- For hyperopia (farsightedness) treatment of patients with refractions less than +0.5 D.
- In eyes with progressive nearsightedness, astigmatism, or farsightedness.
- In eyes with abnormal blood vessels within 1.0 mm of the cornea area where PRK or LASIK will be performed.
- In patients under 18 years of age for mild nearsightedness and under 21 years of age for high nearsightedness with or without astigmatism and farsightedness.
- In patients over the long term. (For PRK surgery: 3 years for nearsightedness, more than 1 year for high nearsightedness with or without astigmatism, or 1 year for farsightedness with or without astigmatism. For LASIK surgery: 6 months for nearsightedness with or without astigmatism, farsightedness with or without astigmatism, or mixed astigmatism.)
- In patients who are taking sumatriptan (Imitrex\*) for migraine.
- In patients who have a tendency to form scars.

- For PRK in patients with nearsightedness greater than -12.0 D or refractive astigmatism greater than 4.0 D.
- For PRK in patients with farsightedness greater than +5.0 D or refractive astigmatism greater than +4.0 D
- For LASIK in patients with nearsightedness greater than -14.0 D or refractive astigmatism greater than 5.0 D.
- For LASIK in patients with farsightedness greater than +5.0 D or refractive astigmatism greater than +3.0 D.
- For LASIK in patients with mixed astigmatism greater than 6.0 D of astigmatism.
- In patients taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery.
- In patients who have had prior incisional refractive surgery.
- For retreatment of farsightedness with astigmatism.

## **Are You a Good Candidate for Laser Vision Correction?**

If you are considering laser vision correction, you must:

- Be at least 18 years of age for PRK treatment of mild nearsightedness or LASIK treatment of high nearsightedness with or without astigmatism.
- Be at least 21 years of age for PRK treatment of high nearsightedness with or without astigmatism or moderate farsightedness with or without astigmatism.
- Be at least 21 years of age for LASIK treatment of moderate farsightedness with or without astigmatism.
- Have healthy eyes that are free from eye disease or corneal

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\* *Imitrex is a registered trademark of Glaxo Group Ltd.*

abnormality (for example, scar, infection, etc.).

- Have nearsightedness (myopia) up to -12.0 diopters with or without refractive astigmatism between 0.75 and 4.0 diopters for PRK treatment.
- Have farsightedness (hyperopia) between +1.0 and +6.0 diopters without astigmatism, or farsightedness between +0.5 and +5.0 diopters with refractive astigmatism between +0.5 and +4.0 diopters for PRK treatment.
- Have nearsightedness up to -14.0 diopters with or without refractive astigmatism between 0.5 and 5.0 diopters for LASIK treatment.
- Have farsightedness between +0.5 and +5.0 diopters with or without refractive astigmatism up to +3.0 D for LASIK treatment.
- Have mixed astigmatism up to 6.0 D of astigmatism for LASIK treatment.
- Have documented evidence that your refraction did not change by more than 0.50 diopter during the year before your pre-operative examination.
- Be informed of laser surgery risks and benefits as compared to other available treatments for nearsightedness (myopia) with or without astigmatism, farsightedness (hyperopia) with or without astigmatism, and mixed astigmatism.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be able to keep your eye accurately on the fixation light for the entire laser surgical procedure.
- Be willing to sign an informed consent form as provided by your eye care professional.

## Before the Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for surgery. This will include a complete physical and eye history, and thorough examination of both eyes. In addition, computerized mapping of your cornea will be done.

### **WARNING:**

**If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks before examination and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce suboptimal surgical results.**

Before the surgery, please tell your doctor whether you take any medications or have any allergies. Also, talk with your doctor about eating or drinking immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You may resume driving only after receiving permission from your doctor.

## The Day of Surgery

Before the surgery you will be asked to listen to the sounds of the treatment so that you will be prepared for the noise the laser makes during surgery. Local anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery.

The PRK surgery begins with removal of the epithelium, the top layer of the cornea. This is done either with the laser or with a small spatula.

The LASIK surgery begins with the placement of a suction ring which elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The movement of the microkeratome in the track of the suction ring cuts a circular corneal flap. This flap of tissue will be lifted by the doctor after the suction is released. Vision will return to the eye after the suction is released.

For both PRK and LASIK surgery, the doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking red light. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the blinking red light. Small amounts of tissue will then be removed from your cornea using the VISX STAR™ Excimer Laser System.

**PRECAUTION:**

**It is very important that you keep looking at the blinking red light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this red, blinking light throughout the treatment to prevent the laser vision correction from being off target.**

Typically, the laser beam will be applied to your eye less than 1 minute and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drops. If PRK surgery was performed, a bandage contact lens or a patch may be placed on your eye.

When the anesthetic drops wear off (about 45 to 60 minutes), your eye may hurt moderately for 1 to 4 days if PRK surgery was performed. Most patients describe this pain as moderate to severe. In LASIK surgery, the discomfort is less severe, typically described

as “a sandy sensation.” Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and to lessen the risk of infection, do **NOT** rub your eyes for the first 3 to 5 **days** after PRK surgery and for 3 to 5 **months** after LASIK surgery.

**IMPORTANT:**

**Your doctor will monitor you for any side effects if topical steroids were used. Possible side effects of prolonged topical steroid use are ocular hypertension, glaucoma, or cataract formation.**

## **After Surgery**

You will be mildly sensitive to light and have the feeling that something is in your eye for the first 4 days. Sunglasses may make you more comfortable during this time.

Your vision should become stable within the first several weeks after surgery. However, you may experience some small changes (for example, improvement or worsening of your vision). These changes may occur up to six months or more after surgery.

A haze or cloudiness may be seen in the cornea following surgery, but usually does not affect your vision. This haze typically disappears over time, but some patients may continue to experience haze.

**IMPORTANT:**

**Use the anti-inflammatory eye drops and lubricants as directed by your doctor. Your laser vision correction results depend upon your following your doctor’s directions.**

## Results from Clinical Studies

The clinical study results of the VISX STAR™ Excimer Laser System were:

### **A. PRK surgery: without the help of glasses (results at 12 months after surgery)**

- 94% mildly nearsighted eyes could see 20/40 or better
- 91% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 90% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 95% moderately farsighted eyes could see 20/40 or better
- 93% moderately farsighted eyes with moderate astigmatism could see 20/40 or better

### **B. PRK surgery: with the help of glasses\* (results at 12 months after surgery)**

- 99% mildly nearsighted eyes could see 20/40 or better
- 98% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 99% moderately farsighted eyes could see 20/40 or better
- 100% moderately farsighted eyes with moderate astigmatism could see 20/40 or better

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\* Data collected from eyes that could see 20/20 or better with glasses before surgery.



**C. LASIK surgery: without the help of glasses (results at 6 months after surgery)**

- 97% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 97% moderately farsighted eyes with moderate astigmatism could see 20/40 or better
- 99% of mixed astigmatic eyes could see 20/40 or better

**D. LASIK surgery: with the help of glasses\* (results at 6 months after surgery)**

- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 100% moderately farsighted eyes with moderate astigmatism could see 20/40 or better
- 100% of mixed astigmatic eyes could see 20/40 or better

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\* *Data collected from eyes that could see 20/20 or better with glasses before surgery.*

## Long Term Post-Treatment Safety Problems

The following is a list of the adverse events and complications that occurred in PRK patients who are **mildly nearsighted (MN)**, **mildly nearsighted with astigmatism (MNA)**, **highly nearsighted with or without astigmatism (HN)**, **moderately farsighted (MF)**, or **moderately farsighted with moderate astigmatism (MFA)** at approximately 1 year after treatment:

<b>Problems</b>	<b>MN (%)</b>	<b>MNA (%)</b>	<b>HN (%)</b>	<b>MF (%)</b>	<b>MFA (%)</b>
<b>Worsening of Best Spectacle Corrected Vision: Significant worsening of vision in the operated eye with the help of glasses (loss of more than 2 lines of vision)</b>	0.4	3.5	2.5	0	0
<b>Increase in Astigmatism: Uneven curving of the cornea by 1 or more diopters that may distort vision and require corrective glasses or contact lenses</b>	3.1	NA*	NA*	0.9	0.8

\* Not available.

<b>Patient Symptoms: Comparison of Vision After Surgery</b>						
	<b>PRK (N = 206) Farsightedness with Astigmatism</b>		<b>LASIK (N = 156) Farsightedness with Astigmatism</b>		<b>LASIK (N = 115) Mixed Astigmatism</b>	
	<b>Worsen 6 Months (N = 203)</b>	<b>Worsen 12 Months (N = 180)</b>	<b>Worsen 3 Months (N = 147)</b>	<b>Worsen 6 Months (N = 144)</b>	<b>Worsen 3 Months (N = 115)</b>	<b>Worsen 6 Months (N = 110)</b>
	<b>%</b>	<b>%</b>	<b>%</b>	<b>%</b>	<b>%</b>	<b>%</b>
<b>Sharpness and Clarity</b>	3.4	6.1	4.8	6.9	6.2	5.5
<b>Consistency of Vision</b>	2.0	1.7	4.1	6.9	5.3	8.2
<b>Sustained Close Work</b>	6.5	10.6	3.4	2.8	NA*	NA*
<b>Daylight Driving</b>	3.0	5.0	4.1	4.2	5.3	4.5
<b>Night Driving</b>	3.0	3.4	4.1	4.9	8.8	2.7
<b>Night Vision with Glare</b>	2.5	3.9	5.4	4.2	7.1	2.7
<b>Reading in Dim Light</b>	4.0	9.0	6.8	6.3	NA*	NA*
<b>General Vision in Dim Light</b>	8.5	14.0	6.8	6.3	5.3	4.5
<b>Overall Visual Comfort</b>	0.0	0.0	5.4	2.1	8.0	8.2

\* Not available.

The following is a list of the adverse events and complications that occurred in LASIK patients at approximately 3 months after treatment for myopia with or without astigmatism.

<b>LASIK Patient Findings (All Eyes)*</b>		
<b>Visual Findings</b>	<b>Percent of Patients Reporting</b>	
	<b>Before LASIK Surgery</b>	<b>3 Months After LASIK Surgery</b>
<b>Severe Glare</b>	<b>9%</b>	<b>6%</b>
<b>Severe Halo</b>	<b>9%</b>	<b>4%</b>
<b>Severe Visual Fluctuations</b>	<b>4%</b>	<b>2%</b>

\* The following adverse events and complications occurred at a rate of less than 1% at 6 months: loss of 2 or more lines of BSCVA (0.5%), BSCVA worse than 20/40 (0.4%), BSCVA less than 20/25 when the pre-operative eye was 20/20 or better (0.4%), and wrinkling of the LASIK cap (0.3%).

There were no adverse events or complications that occurred in LASIK patients at approximately 6 months after treatment for either hyperopia with or without astigmatism or for mixed astigmatism.

## **Questions to Ask Your Doctor**

You may want to ask the following questions to help you decide if laser vision correction is right for you:

- What other options are available for correcting my vision?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of laser vision correction for my amount of refractive error?
- What vision can I expect in the first few months after surgery?
- If laser refractive surgery does not correct my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?

- Will I be able to wear contact lenses after laser surgery if I need them?
- How is laser surgery likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having laser surgery?
- Should I have laser surgery in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have laser surgery only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser vision correction is not covered by most health insurance policies.

## Self-Test

### Are You an Informed and Educated Patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Laser refractive surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. Laser surgery is the same as radial keratotomy (RK).	<input type="checkbox"/>	<input type="checkbox"/>
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
4. The laser does all the work; I just have to lie on the chair.	<input type="checkbox"/>	<input type="checkbox"/>
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	<input type="checkbox"/>	<input type="checkbox"/>
6. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk that I may lose some vision after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. It doesn't matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
9. If I have an autoimmune disease, I am still a good candidate for laser vision correction.	<input type="checkbox"/>	<input type="checkbox"/>

Answers to SELF-TEST are found on page 23.

## Summary of Important Information

- Laser vision correction is a permanent operation to the cornea and is irreversible.
- Laser vision correction may not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before laser vision correction. You will need written evidence that your nearsightedness with or without astigmatism or farsightedness has changed less than 0.50 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- Laser vision correction may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- PRK and LASIK are not laser versions of radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK are completely different from RK and ALK.
- Alternatives to PRK and LASIK include, but are not limited to, glasses, contact lenses, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.
- Before considering laser vision correction you should:
  - a. Have a complete eye examination.
  - b. Talk with one or more eye care professionals about the potential benefits of laser refractive surgery, and the complications, risks, and time required for healing.

## **Answers to Self-Test Questions:**

**1.** False (see Risks on page 6); **2.** False (see What are PRK and LASIK? on page 5); **3.** False (see Before The Surgery on page 12); **4.** False (see The Day of Surgery on page 12); **5.** True (see Benefits on page 6); **6.** True (see What are PRK and LASIK? on page 5); **7.** True (see Risks on page 6); **8.** False (see Contraindications on page 7); **9.** False (see Contraindications on page 7).



## Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

**Antibiotic Medication:** a drug used to treat or prevent infection.

**Anti-inflammatory Medication:** a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

**Astigmatism:** The cornea and lens focus light rays from horizontal and vertical lines at different distances from the retina. The multiple focal distances result in blurred vision. Astigmatism may occur along with nearsightedness (myopic astigmatism), farsightedness (hyperopic astigmatism), or a combination of nearsightedness and farsightedness (mixed astigmatism).

**Automated Lamellar Keratectomy (ALK):** a type of surgery used to correct vision by removing a cap of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

**Cataract:** an opacity or clouding of the lens inside the eye that can cause a loss of vision.

**Collagen Vascular Disease:** a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

**Contraindications:** any special condition that results in the treatment being inadvisable.

**Cornea:** the clear front surface of the eye. Surgery such as PRK and LASIK reshape or flatten this surface to correct vision.

**Corneal Epithelium:** the top layer of the cornea. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

**Corneal Haze:** a cloudiness of the cornea that may occur after PRK and LASIK.

**Corneal Ulcer:** an infection of the cornea that may result in a loss of vision.

**Diopter (D):** a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

**Farsightedness:** The cornea and lens focus light rays beyond the retina, causing objects to appear blurry. Hyperopia is another term for farsightedness.

**Glaucoma:** a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

**Halos:** circular flares or rings of light that may appear around a headlight or other lighted object.

**Herpes Simplex:** a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body.

**Herpes Zoster:** a type of infection caused by a virus that can recur. Vesicles typically appear on only one side of the body.

**Highly Nearsighted:** nearsightedness greater than -6 diopters.

**Hyperopia:** The cornea and lens focus light rays beyond the retina, causing objects to appear blurry. Farsightedness is another term for hyperopia.

**Immunodeficiency Disease:** a condition that alters the body's ability to heal. An example is AIDS.

**Intraocular Pressure (IOP):** fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

**Keratoconus:** a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

**LASIK:** a type of surgery used to correct vision by raising a flap of cornea using a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

**Lens:** a structure inside the eye that helps to focus light onto the back of the eye.

**Mildly Nearsighted:** nearsightedness between -1.0 and -6.0 diopters.

**Moderately Farsighted:** farsightedness between +1.0 and +6.0 diopters.

**Myopia:** The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

**Nearsightedness:** The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

**Ocular Hypertension:** an increase in the pressure inside the eye.

**Photorefractive Keratectomy (PRK):** a type of surgery used to correct vision by reshaping the cornea using an excimer laser.

**Radial Keratotomy (RK):** a type of surgery used to correct vision by flattening the cornea with a scalpel.

**Re-epithelialization:** regrowth of the top layer of the cornea. The epithelium is removed before the PRK treatment and usually grows back within a few days after the treatment.

**Refractive Error:** parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

**Regression:** a decrease in the amount of vision correction after PRK or LASIK surgery.

**Retina:** the back surface of the eye. The retina takes focused light and transfers it to the brain.

# Patient Assistance Information

## Primary Eye Care Professional

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

## Laser Vision Correction Doctor

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

## Treatment Location

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

## Laser Manufacturer:

**VISX, Incorporated**  
3400 Central Expressway  
Santa Clara, CA 95051  
U.S.A.  
Tel: 408.733.2020